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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,034	02/09/2004	Stephanie M. Kladakis	022956-0260	6915

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EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/775,034	KLADAKIS ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9,10,13-18,20,21,24-28,30-39 and 42-53* is/are pending in the application.

4a) Of the above claim(s) *32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9,10,13-18,20,21,24-28,30,31,34-39 and 42-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/08 has been entered.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS included with the current action and prior actions have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in any of the IDS previously submitted which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 43,47,49,53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 43,47,49,53 claim "the cells of the native tissue", and is therefore positively claiming a living tissue. The living matter "cells" of the present invention is not the result of human intervention; it is of nature, which has been held not patentable.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39,42-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al. (6005161). Brekke et al. disclose (Figs. 1-4) a porous tissue scaffold formed of a bioresorbable, synthetic polymer, col. 5, lines 6-15. It can be seen the implant comprises at least one pocket or void, col. 7, lines 37-40. Brekke discloses to include tissue or cells in the pockets or voids that can migrate into the scaffold's structure, col. 10, lines 42-47. The voids cause the implant to have hollow interior sections or lumens. Brekke additionally teaches to use harvested tissue, col. 10, lines 54-67. Common sense would be used in harvesting the tissue in that the surgeon, doctor or specialist would remove healthy tissue to form or provide the grafting material. No doctor, surgeon or specialist would use diseased tissue on a patient and risk the possibility of causing the patient more harm. However, Brekke et al. do not explicitly state the shape of the implant is "wedge-shaped". It is noted that Brekke does teach the device can be wedged into the defect or cavity of

repair, see abstract. It would have been obvious to one of ordinary skill in the art to modify the shape to be "wedge-shape" since such a modification only involves routine skill in the art. A change in shape or form is recognized as being within the skill of a normal artisan in the art, absent any showing of unexpected results. *In re Dailey* et al., 149 USPQ 47. Regarding claims 3,4,15,16,25,26,36,37 Brekke discloses the implant can include a bioactive substance such as cartilage Proteins, col. 10, lines 17-41. With respect to claims 5,6,17,18,27,28 any 3-dimensional object inherently has top and bottom portions which are arbitrary. The porous scaffold has an internetwork to connect the portions. Cells of the native tissue are capable of populating the scaffold. Regarding claims 13,34 Brekke discloses the tissue placed in the "pocket" or voids can be construed to be either minced, sliced or slivered, col. 6, lines 1-4, col. 10, lines 13,14. Regarding claim 24, Figs. 5,6 show the step of loading viable tissue into the pockets of the tissue scaffold. Brekke discloses the step of implanting, col. 12, line 3.

With respect to claims 44, 45,50,51 Brekke does disclose the tissue size can be optimized to the desired need of the patient, col. 11, lines 14-15. It would have been obvious to one of ordinary skill in the art to find the optimal size of the tissue fragments to be used in the composite implant. Thus, it would have been an obvious expedient to have a thickness range of 200μm to 3mm for the tissue fragments or a particle size in the range of $0.5mm^3$ to about 3 mm^3 since such a modification only involves routine skill in the art absent a showing of unexpected results.

Claims 1, 3-6,9,10,13-18,20,21,42-47 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, claims 1,3-6,9,10,13-18,20,21,24-28,30,31,34-

39,42-53 are rejected under 35 U.S.C. 103(a) as obvious over Schwartz et al. (2003/78617). Please note the Examiner is interpreting claims 1,13 as product-by-process claims including the limitation of "harvested from healthy tissue." In an ex parte case product-by-process claims are not construed as being limited to the product formed by the specific processes recited. In re Hirao, 535 F2d 67, 190 U.S.P.Q. 15 see footnote 3 (CCPA 1976). Clearly one of skill in the art would harvest tissue from a healthy organ, bone, soft tissue or other areas of the body to obtain graft material. A surgeon or doctor with common sense would not graft diseased tissue to use in a patient and risk the unsuccessful result of not repairing the defect because of using diseased tissue. Thus, the tissue obtained in the Schwartz device is fully capable of being harvested from "healthy tissue." Fig. 17 shows a wedge-shaped tissue scaffold. Schwartz et al. disclose the tissue repair device comprises a porous resorbable material, paragraphs 16,17. Schwartz also discloses the material can be synthetic, paragraphs 83,86,94. It can be seen the implant includes top and bottom portions **24**,**26** respectively. Fig. 34 illustrates the top and bottom portions can be mated to one another. Schwartz discloses the implant pocket material can be an ECM. The examiner is interpreting the claimed elements "viable tissue" in this way: capable of working or being used. Claims in a pending application should be given *their broadest reasonable interpretation*. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Since Schwartz discloses material that is fully capable of being used and working in the body to repair the defect, it is viable. Schwartz additionally shows (Fig. 23) that there is a tissue material **22** placed in a pocket or

hollow interior or lumen that extends from the greater height to the tapered smaller end and is formed between the top and bottom portions. Bioactive substances can be added to the tissue material, paragraphs 130,131. Schwartz et al. disclose that tissue is obtained and comminuted (i.e. mince, slice or sliver) to smaller fragments and then loaded between or within the pocket of the tissue scaffold, paragraphs 16,17,83. Schwartz et al. disclose that osteoblasts are one type of cells placed therein, paragraph 133. Budny (2005/147645) teaches that an ECM provides the necessary framework for cell migration, such as osteoblasts, paragraph 25. Thus, it is inherent that the cells of Schwartz's implantable device migrate into the scaffold. Figs. 26 and 31 show the implantation is done such that native tissue **12** abuts the opening of the pocket to maintain the tissue **22** therein. Regarding claims 42,43,46-49,52,53 since the ECM **21** covers a portion of the native tissue **12** (Fig. 19) it can be construed that the cells populate a portion of the scaffold and cells from the native tissue populate a portion of the scaffold that lie beneath that portion of the scaffold. With respect to claims 44,50 Schwartz discloses the size of the fragment or tissue can be about 200μm, paragraph 122.

Regarding claims 24-28,30,31,34-39,42-53, it is noted that Schwartz et al. do not explicitly state the viable tissue is obtained from that harvested from healthy tissue. Clearly the ability to obtain healthy tissue for use as graft material is recognized as part of the skill and ordinary capabilities of one skilled in the art. Finding healthy tissue for use as tissue repair material would have been the objective for a doctor treating a patient needing treatment. The doctor clearly would determine that the tissue harvested

from the donor is healthy and suitable to treat a patient in need of repair of a defect. It would have been obvious to one of ordinary skill in the art to find healthy tissue and use it for the viable tissue to be placed in the pocket of the tissue scaffold of Schwartz's device to increase the suitability of the implant placed in the patient by providing the predictable result of using a non-disease transmitting material in the patient.

With respect to claims 45,51, it is noted that Schwartz does disclose that the particle size can be any dimension and is not to be limited to particular dimensions, paragraph 122. However, Schwartz fails to explicitly disclose the tissue fragments are of a particle size having the dimension of 0.5 mm^3 to 3 mm^3. It would have been obvious to one of ordinary skill in the art to utilize a particle dimension as claimed since such a modification only involves routine skill in the art and varying the size would not affect the function of the cells to carry out a process.

Response to Arguments

Applicant's arguments filed 9/2/08 have been fully considered but they are not persuasive. Applicant argues that the tissue used in the Schwartz device is not considered "viable tissue." However, as mentioned above, the Examiner has interpreted the term "viable" as capable of working and clearly if the tissue material of Schwartz was not capable of working then it would not have been selected for use in the repair device. Second, the Examiner clearly has referred to where Schwartz discloses tissue material and thus meets the requirements of the claim. Applicant attempts to define "tissue" with a special definition in the arguments but has not clearly

set this definition forth in the written disclosure as filed. Thus, since the material of tissue in Schwartz's device is derived from natural tissue, it can still be considered "tissue" and capable of being used in the body it is thus "viable". Applicant argues that the Examiner's interpretation cannot be given to the terms since they would not be considered in the context of the disclosure. However, the Examiner respectfully disagrees since if the material is capable of being used in the body, it must be biocompatible and thus can be considered viable. Applicant then argues that there are cells that can migrate and populate the scaffold. Schwartz clearly discloses that there are cells also in the pocket that are fully capable of migrating into the scaffold. Applicant then attempts to use this limitation to argue "viable" means something other than what the Examiner is considering "viable." Applicant then presents a new limitation of the tissue being "harvested from healthy tissue" to also try to define "viable". However, it should be noted that the claims use comprising as a transition phrase and that the tissue includes or has cells. Clearly, the Schwartz material is tissue and it contains cells to thus meet the claim limitations. As far as the new limitation the Examiner has addressed it above and any one of ordinary skill in the art would use "healthy tissue" as this is common sense. A doctor would not harvest diseased tissue to use as graft material or tissue to be placed in a patient.

Applicant in conclusion argues the 103 obvious rejection over size dimensions and states some reference provides criticality into why the dimensions are important. However, there is no mention of where some criticality is found in the written disclosure. The Examiner notes some preferences are mentioned in paragraph 61, but fail to state

any advantages or unexpected results were obtained from some experiment. The Examiner is unconvinced.

Applicant's arguments with respect to claims 1,13,24,34 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738